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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,916	10/02/2000	Carl Anthony Blau	UO FWI 15624	4343

26389 7590 06/18/2002

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[REDACTED] EXAMINER

BECKERLEG, ANNE M

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/582,916	BLAU ET AL.
Examiner	Art Unit	
Anne Marie Becherleg	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 April 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-88 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <i>detailed action</i> .      |

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### **DETAILED ACTION**

Applicant's response to the election/restriction requirement received on 4/1/02 has been entered. Applicant's election of the species thrombopoietin receptor is acknowledged. However, please note that this application has been subjected to new grounds of election/restriction, see below. Thus, the previous election/restriction requirement mailed on 12/19/01 has been withdrawn in view of the new grounds for restriction presented below.

#### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-42, 44-53, 55-66, 70-88, drawn to methods of expanding a primary population of cells and methods of treating or preventing a disease or pathological condition using said cells, classified in classes 435 and 424, subclasses 325 and 93.2 respectively.
2. Claims 21, 43-44, 54-55, 65 and 67-69, drawn to methods of expanding a primary population of cells and methods of treating hematopoietic disease comprising cells which have been transduced with a first recombinant DNA encoding a fusion protein, and a second recombinant DNA construct encoding a therapeutic gene.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I-II are patentably distinct in that the cells of Invention II, which comprise a second recombinant DNA construct which encodes a therapeutic gene in addition to the first recombinant DNA construct which encodes a fusion protein, are substantially different in physical, chemical, and biological properties than cells which comprise the first DNA construct which encodes a fusion protein. The second recombinant DNA construct is not required to make the cells of invention I, and further the cells comprising the second recombinant DNA construct can be used for substantially different purposes than those of Invention I, such as the production of the therapeutic protein encoded by the second DNA construct in vitro or in vivo.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of primary mammalian cells

- a) hematopoietic cells
- b) hematopoietic stem cells
- c) hepatic cells
- d) muscle cells
- e) nerve cells

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- f) cartilage cells
- g) bone cells
- h) intestinal cells
- I) pancreatic cells
- j) kidney cells
- k) CNS stem or progenitor cells
- l) embryonic stem cells

Please note that the species identified above represent cells with vastly different physical characteristics and biological properties. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of immunomodulatory molecule from the group a)-l) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Claims 1-2, 5-22, 25-42, 44, 47-53, 55 and 39-54 are generic for Invention I. Claims 21, 44, and 65 are generic for Invention II.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

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of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The

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technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

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